

**STATE OF NEW MEXICO
COUNTY OF DOÑA ANA
THIRD JUDICIAL DISTRICT COURT**

THE STATE OF NEW MEXICO, EX
REL. HECTOR BALDERAS,
ATTORNEY GENERAL,

Plaintiff,

v.

STERIGENICS U.S., LLC, SOTERA
HEALTH HOLDINGS, LLC, SOTERA
HEALTH LLC, AND SOTERA
HEALTH COMPANY,

Defendants.

No. D-307-CV-2020-2629

(Judge Beyer)

UNITED STATES' AMICUS CURIAE BRIEF

On April 14, 2021, Plaintiff the State of New Mexico filed an Emergency Motion for Temporary Restraining Order and Preliminary Injunction. This brief is filed in response to the Court's April 22, 2021 order. In its order the Court asks the United States Environmental Protection Agency (EPA) to provide its views on the issues raised in Plaintiff's motion, including the impact of the doctrine of primary jurisdiction with respect to EPA. With respect to EPA's role, the Court should decline to invoke the doctrine of primary jurisdiction to stay or dismiss this action.

Additionally, we note that the parties have cited EPA-generated documents in this action, and we clarify the typical function of those documents in the background section below. The United States, in this brief, does not address the applicability of primary jurisdiction with respect to the role of the New Mexico Environmental Department.

BACKGROUND

I. Statutory and Regulatory Background

A. The Clean Air Act

The Clean Air Act, 42 U.S.C. §§ 7401-7671q, sets up a comprehensive program for control of air pollution through a system of shared federal and state responsibility. EPA sets national air quality standards and provides oversight and enforcement. 42 U.S.C. § 7409. Pursuant to CAA section 110, States must then establish “State implementation plans” (SIPs), which impose controls on individual sources of air pollution as necessary to attain and maintain the national standards. 42 U.S.C. § 7410. The SIP requires State rulemaking action followed by review and approval of State plans by EPA at the federal level.

The 1990 CAA Amendments established a two-phase approach to control emissions of hazardous air pollutants. The first phase involves EPA setting technology-based emission standards. 42 U.S.C. § 7412(d)(d). The second phase requires EPA, after considering costs, to determine whether the residual risks that

remain warrant more stringent standards. 42 U.S.C. § 7412(f). CAA Section 112 requires EPA to establish emission standards for “major” and “area” sources of hazardous air pollutants. 42 U.S.C. § 7412. A “major” source is a stationary source that has the potential to emit 10 tons per year or more of any hazardous air pollutant or 25 tons per year or more of any combination of hazardous air pollutants. *Id.* § 7412(a)(1). An “area” source is any stationary source that is not a major source. *Id.* § 7412(a)(2). CAA Section 112(b)(1) lists pollutants to be regulated within industrial source categories. 42 U.S.C. § 7412(b)(1). Ethylene oxide is a listed hazardous pollutant. *Id.* Section 112(c)(1) requires EPA to publish a list of categories of sources emitting listed hazardous air pollutants. 42 U.S.C. 7412(c)(1). A “category” of sources is a group of sources having common features, suggesting they should be regulated in the same way.

SIPs require many industrial sources of pollution to obtain preconstruction permits through a process called “New Source Review.” *Id.* § 7475(a). Such New Source Review permits may incorporate section 112 standards.

B. EPA’s Nationwide Regulation of Ethylene Oxide Commercial Sterilization Facilities

On July 16, 1992, EPA published a list of major and area sources that required the promulgation of section 112 standards (i.e., the source category list). 57 Fed. Reg. 31576. Ethylene oxide commercial sterilization and fumigation

operations were one of the listed categories. *Id.* EPA first published hazardous air pollutant standards for these commercial sterilization facilities more than twenty-five years ago. *See* 59 Fed. Reg. 62585 (Dec. 4, 1994). As part of this regulatory process EPA set major source and area source standards for those facilities. *See* 59 Fed. Reg. 62586. The current ethylene oxide emission standards are available at 40 C.F.R. part 63, subpart O.

The process of ethylene oxide sterilization typically occurs in a sterilization chamber, and there are three major emission points: (1) the sterilization chamber vent; (2) the aeration room vent; and, (3) the chamber exhaust vent. 84 Fed. Reg. 67892. The sterilization chamber vent evacuates ethylene oxide from the sterilization chamber following sterilization, fumigation, and any subsequent gas washes. *Id.* The aeration room vent evacuates ethylene oxide from the aeration room (where sterilized materials off-gas following sterilization). *Id.* The chamber exhaust vent evacuates ethylene oxide-laden air from the sterilization chamber after the chamber door is opened for product unloading following the completion of sterilization and associated gas washes. *Id.* In the initial 1994 regulation of ethylene oxide sterilization facilities EPA regulated all three major emission points. Those regulations were later subject to a series of revisions due, in part, to a series of explosions at sterilization facilities. 84 Fed. Reg. 67892. EPA's regulations

currently require no controls for emissions from the aeration room vent or the chamber exhaust vent. *See* 40 CFR part 63, subpart O.

Ethylene oxide emissions can also occur from sources other than the aeration room vent, sterilization chamber vent, or the chamber exhaust vent – such emissions are considered “fugitive emissions.”¹ EPA, to date, has not set standards for fugitive emissions from ethylene oxide commercial sterilization facilities. 84 Fed. Reg. 67892. In 2019, however, EPA issued an advanced notice of proposed rulemaking that solicited information to aid in potential future revisions to ethylene oxide emission standards for commercial sterilization facilities. 84 Fed. Reg. 67889. In this advanced notice EPA solicits information that will aid in future revisions to the ethylene oxide emissions standards for sterilization facilities. *Id.*

Potential revisions being considered include developing control measures for fugitive emissions as well as promulgating additional safety measures for chamber exhaust vents, and other improvements. *Id.* Since 2019 EPA has issued several information collection requests that are intended to better understand ethylene oxide emission sources, measurement and monitoring techniques, and available control

¹ Fugitive emission are emissions that could not reasonably pass through a stack, chimney, vent, or other functionally-equivalent opening. *See* 40 C.F.R. §§ 70.2, 71.2 (defining “fugitive emissions” under Clean Air Act Title V). For purposes of regulation of ethylene oxide, fugitive emissions are considered to be “those emissions which are not routed to an existing pollution control device.” 84 Fed. Reg. 67894.

technologies. *See* 86 Fed. Reg. 24862 (May 10, 2021, proposed information collection request); 85 Fed. Reg. 35931 (June 12, 2020, proposed information collection request). This regulatory process is ongoing.

C. EPA’s delegation of permitting authority to New Mexico

Congress, in the Clean Air Act, recognizes that air pollution and control is the “primary responsibility of States and local governments.” *Id.* § 7401(a)(3).

Accordingly, when a state adopts a SIP that state must provide for “implementation, maintenance, and enforcement” of air quality standards for all CAA regulated pollutants. *Id.* § 7410(a)(1). New Mexico has been administering its SIP for almost 50 years.²

Section 112(l) of the CAA and 40 CFR part 63, subpart E, authorizes EPA to delegate authority for the implementation and enforcement of emission standards for hazardous air pollutants to a State that satisfies the statutory and regulatory requirements in subpart E. 42 U.S.C. § 7412(l); 40 C.F.R. Part 63.12(b) (addressing EPA’s authority to delegate administration of hazardous air pollutant standards). The hazardous air pollutant standards include standards for ethylene oxide. *See* 40 C.F.R. part 63, subpart O.

² *See* 40 CFR Part 52, Subpart GG, §§ 52.1620 - 52.1640 (providing the status of the New Mexico SIP).

EPA has delegated to New Mexico the authority to administer the state's program implementing specified new source performance standards and national emission standards for hazardous air pollutants. 83 Fed. Reg. 46107. This delegation includes authority to administer standards for ethylene oxide sterilizers. 83 Fed. Reg. 46112 (showing the delegation status in New Mexico for Part 63 standards).

Permits in New Mexico are issued pursuant to New Mexico's Air Quality Control Act and regulations adopted pursuant to that act, including Title 20, Chapter 2, Part 72, 77, 78 and 82 of the New Mexico Administrative Code (establishing New Mexico's new source performance standard program and New Mexico's program for national emission standards for hazardous air pollutants). Pursuant to those provisions, and potential others, New Mexico administers Clean Air Act programs relevant to the facility at issue in this case.

II. Factual Background

A. Permitting and allegations concerning the Santa Theresa Facility

Defendants Sterigenics U.S. LLC, Sotera Health Holdings, LLC, Sotera Health LLC, and Sotera Health Company (collectively, Defendants) own and operate an industrial sterilization and fumigation facility in Santa Theresa, New

³ This factual summary is based on factual allegations contained in New Mexico's complaint. The United States has not independently verified the accuracy of those allegations.

Mexico.³ Complaint ¶ 3. At this facility Defendants use substantial quantities of ethylene oxide. Complaint ¶ 6.

The Santa Theresa facility operates under an Air Quality Bureau New Source Review permit issued by the New Mexico Environment Department. *See* Sterigenics Air Quality Permit, attached as Ex. A to Declaration of Steve Ortiz, Dkt. 14-1 in Civil Action No. 2:20-cv-01355-KG-KRS. This is a “permanently applicable” permit issued in response to a prior modification of the Sterigenics facility. *See* Permit §§ A101-102. While the Sterigenics facility permit addresses some forms of ethylene oxide emissions, it does not address fugitive emissions (though this is not surprising because, as noted above, EPA has not, to date, established fugitive emission standards for ethylene oxide). *See* Sterigenics Air Quality Permit.

In this action New Mexico alleges that Defendants have caused “substantial unreported, uncontrolled releases” of ethylene oxide. Complaint ¶ 19. Allegedly, these uncontrolled releases are due to lax oversight of Defendants’ operation, including leaving open sterilization chamber doors, improperly washing equipment, and causing delivery of sterilized products that were off-gassing during the delivery process. *Id.* New Mexico also alleges that mechanical failures and breakdowns led to additional uncontrolled emissions of ethylene oxide. Complaint ¶ 20. New

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Mexico's state-law based tort claims are based on alleged harms associated with these emissions. Complaint ¶¶ 53-222. New Mexico has not alleged any federal claims and has not asserted claims based on a violation of the state-issued permit.

B. EPA's Integrated Risk Management System and National Air Toxics Assessment

Both Plaintiff and Defendant cite to an assessment of ethylene oxide carcinogenicity released in 2016 by EPA's Integrated Risk Information System (IRIS). Additionally, the parties cite to EPA's 2014 National Air Toxics Assessment. Both the utility and limitations of each of those documents are important to understand.

EPA's IRIS program identifies and characterizes health hazards found in the environment. *See* <https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system>. IRIS uses assessments, among other tools, to identify potential hazards associated with exposure to a particular chemical and to characterize the "dose-response assessment" (how much chemical exposure results in a health hazard). *Id.* EPA's IRIS evaluation on the inhalation carcinogenicity of ethylene oxide is intended to characterize the hazards posed by a particular hazardous substance. That evaluation is not intended to be a facility-specific assessment, and does not seek to conclude that any facility either does, or does not, pose a specific risk to local populations under particular conditions. EPA acknowledges that the

information presented in its 2016 evaluation of ethylene oxide may be relevant to this action, though we caution that the EPA assessment focuses generally on potential hazards posed by the substance itself, and not to any factors associated with any individual facility or the population near any specific facility.

EPA's 2014 National Air Toxics Assessment (NATA) was developed as a screening tool for state, local and tribal air agencies. *See* <https://www.epa.gov/national-air-toxics-assessment/nata-overview>. This tool helps those agencies to identify likely emission sources for pollutants and identify areas that they may wish to study further. *Id.* EPA cautions, however, that more localized studies are often needed to better characterize local-level risk. *Id.* The 2014 NATA includes a map application that allows users to display risks, emission and other NATA data on a map. These maps include layers of data that can be accessed in a variety of ways. A users guide to the mapping application is available at <https://gispub.epa.gov/NATA/2014NATAmapappuserguide.pdf>.

Though extremely useful, NATA has limitations. *See* <https://www.epa.gov/national-air-toxics-assessment/nata-limitations> (listing limitations). Pollutant concentrations used in risk calculations may be based on model simulations, not direct measurements. *Id.* The assessment incorporates assumptions. *Id.* Additionally, there are often data gaps. *Id.* Because of these limitations, NATA's results are best applied to larger areas, not to specific places.

Those results are best applied over time, and assume that exposed individuals breathe targeted toxins daily over a 70 year period. *Id.*

When EPA becomes aware of a data gap the agency issues a “NATA Emissions Update,” a document that provides a list of some of the issues that either were not addressed during the review of a prior assessment, or were not known at the time of a prior assessment. On July 28, 2020, EPA issued the 2014 NATA Emissions Updates. *See* Ex. M to Sterigencis Preliminary Injunction Opposition. EPA notes in the 2014 NATA Emissions Updates document that the Santa Teresa facility installed a control devise between 2014 and 2016. The 2014 NATA assessment is based on data that does not account for newly installed emissions control devices, thus EPA stated that the OIG “erroneously included the Sterigenics Santa Teresa Facility in its list of facilities for follow-up.” Ex. L to Sterigencis Preliminary Injunction Opposition. This conclusion is based on a data gap. EPA has insufficient data to determine whether follow up is or is not necessary. EPA did not determine that the data indicates that additional investigation would be inappropriate.

DISCUSSION

The doctrine of primary jurisdiction facilitates coordination between judicial and administrative governmental entities. *See generally, United States v. Morgan*, 307 U.S. 183, 191 (1939) (recognizing that courts and agencies should work in a

coordinated fashion). This doctrine, which arises where both a court and an administrative agency have concurrent jurisdiction, “is a prudential rule used by courts to allocate between courts and agencies the initial responsibility for resolving a dispute when their jurisdictions overlap.” *Eldridge v. Circle K Corp.*, 934 P.2d 1074, 1078-79 (N.M. S.Ct., 1997). In some circumstances a court may refer the resolution of underlying matters to an agency with specialized knowledge, however technical or expert knowledge may not be necessary where a question is “within the conventional competence of the courts.” *Id.* at 1079, quoting *Nader v. Allegheny Airlines, Inc.*, 426 U.S. 290, 305–06 (1976). The decision whether to invoke primary jurisdiction should be based on “ ‘which course would best serve the ends of justice.’ ” *State ex rel. Norvell v. Arizona Public Service Co.*, 510 P.2d 98, 104 (N.M. S.Ct. 1973). The United States is not aware of an available administrative remedy through EPA that requires coordination between this court and EPA and is not aware of any ongoing rulemaking that would form a proper basis for the invocation of primary jurisdiction. Accordingly, invoking primary jurisdiction to stay or dismiss this case would not serve the ends of justice.

While there is no “fixed formula” governing application of the doctrine, in general, the factors that courts evaluate include (1) whether the issue is a question within an agency’s particular field of expertise, (2) whether the issue is particularly within the agency’s discretion, (3) whether there is a substantial risk of inconsistent

rulings, and (4) whether a prior application to the appropriate agency has been made. *See, e.g., U.S. v. Western Pacific Railroad Co.*, 352 U.S. 59, 62–63 (1956); *Raritan Baykeeper v. NL Indus., Inc.*, 660 F.3d 686, 691 (3d Cir. 2011). This doctrine seeks to allocate “law making power” to administrative agencies in certain circumstances. *Western Pacific Railroad Co.*, 352 U.S. at 65.

All four factors weigh against the application of primary jurisdiction here. While EPA has authority over environmental matters, that authority is not exclusive. With respect to the first factor, neither EPA’s expertise nor any exercise of EPA discretion warrants an exercise of primary jurisdiction to stay or dismiss New Mexico’s action. The expertise of a technically expert body may not be needed if the question to be resolved is “within the conventional competence of the courts.” *Nader v. Allegheny Airlines, Inc.*, 426 U.S. 290, 305–06, 96 S.Ct. 1978, 1987–88, 48 L.Ed.2d 643 (1976) (in an ordinary fraud action against an airline, expertise of the Civil Aeronautics Board, which had concurrent jurisdiction, was not likely to be helpful). EPA, as a regulator, has expertise regarding the types of harms posed by ethylene oxide and the types of controls that are necessary to minimize those harms. But EPA has no particular knowledge of the facts regarding the Santa Theresa facility, and this Court has the necessary tools to develop that facility-specific knowledge. *See generally Reiter v. Cooper*, 507 U.S. 258, 269 (1993) (rejecting argument that the doctrine of primary jurisdiction could be used to compel agency

review even where an agency has relevant concurrent jurisdiction). Additionally, the legal questions at issue in this case are primarily questions of New Mexico State law, and EPA has no expertise regarding New Mexico tort law. In *U.S. v. Western Pacific* the Supreme Court examined whether, in order to effectuate the statutory purposes of the Interstate Commerce Act, a reviewing court was required to allow the Interstate Commerce Commission to construe a tariff issue before that same issue was construed by a reviewing court. *Id.* at 65. The Supreme Court focused on whether the particular expertise of the agency was vital to inform the legal question presented to the court, concluded that knowledge of “intricate facts” about the transportation sector was necessary to interpret the meaning of the key term at issue in that case, and held that the Interstate Commerce Commission had the necessary knowledge. *Western Pacific*, 352 U.S. at 66. There is no parallel here. This is because New Mexico has posed questions of New Mexico state law, because the underlying facts will be developed through discovery, and because the legal questions go to whether Plaintiff can prove that Defendants emissions caused a harm that is actionable in New Mexico. There is no federal statutory purpose here that would be best effectuated by allowing EPA action.

With respect to the second factor, EPA does not have particular discretion over enforcement of air-related tort actions. EPA does not have exclusive discretion even over permit enforcement actions. This is true even if New Mexico tort law

requires consideration regarding the scope of, and compliance with, the state-issued permit at the Santa Theresa facility. Congress contemplated a structure that would allow state and citizen actors to litigate such questions. 42 USC 7604 (citizen suit enforcement provision). The Clean Air Act also expressly provides for enforcement of state law provisions with respect to air emissions. The states' rights savings clause of the Clean Air Act provides:

Except as otherwise provided ... nothing in this chapter shall preclude or deny the right of any State or political subdivision thereof to adopt or enforce (1) any standard or limitation respecting emissions of air pollutants or (2) any requirement respecting control or abatement of air pollution....

42 U.S.C. § 7416. Consistent with that statutory provision, EPA regulations recognize that states may adopt air emission standards, limitations, provisions or regulations that are more stringent than federal standards, under specified circumstances. 40 C.F.R. § 63.12(a). Thus, not only is EPA expertise not particularly relevant with respect to the New Mexico tort issues that are central to this action, Congress also contemplated that both state and citizen enforcers would independently litigate even permitting issues. It would be inconsistent with Congressional intent for this Court to exercise its discretion and decline to consider New Mexico's claims.

The third factor also weighs against an exercise of primary jurisdiction. "The court in its discretion may defer to an administrative agency in the interests of

judicial economy, where the agency is in a better position to fully develop a record of the grievance.” *McDowell v. Napolitano*, 895 P.2d 218, 222 (N.M. S.Ct. 1995). Here, however, EPA is not currently engaged in an administrative enforcement action against Sterigenics with respect to its New Mexico facility and EPA is not in a better position to develop the factual record relevant to New Mexico’s claims. Additionally, EPA cannot be compelled to file such an action. *Heckler v. Chaney*, 470 U.S. 821 (1985) (recognizing that an agency’s decision not to exercise certain enforcement actions is not subject to judicial review). Put another way, there is not a pending administrative action that would form the basis for an inconsistent ruling with this Court.

With respect to the fourth factor, there has been no “application” to EPA to assess the particular facts of this case. As mentioned in the prior paragraph, EPA has not undertaken an administrative enforcement action with respect to Sterigenics’ Santa Theresa facility. EPA has issued an advanced notice that it is collecting information in support of a future proposed nationwide rule that, if finalized as proposed, could set nationwide regulations for fugitive emissions from ethylene oxide sterilization facilities like the facility at issue in this case. 84 Fed. Reg. 67889. EPA’s rulemaking process is ongoing, however, and could be finalized in a different form than anything suggested in the advanced notice. Additionally, it is

unclear that any such nationwide regulation, if promulgated, would be relevant to New Mexico's claims in this case.

The rulemaking process is lengthy. Any change the national emission standards for the ethylene oxide commercial sterilization the agency would first require EPA to publish a Notice of Proposed Rulemaking in the Federal Register, notifying the public of the agency's plan to address a problem and providing an opportunity for public comment. EPA would specify a timeframe for comments to be submitted – for complex rulemakings EPA often provides lengthy comment periods of 180 or more days. The agency must then consider, and respond to, all “significant” public comments and develop a final rule. *Perez v. Mortgage Bankers Ass’n*, 575 U.S. 92, 95 (2015). At that point EPA may publish a final rule that sets an effective date for the proposed regulations. This process often takes years to complete. The potential of future EPA regulation, regulation which would take place on an unspecified timeline if it occurred at all, that may or may not be relevant to the analysis in this case, forms an insufficient sufficient basis to invoke primary jurisdiction here. This is especially true because any EPA nationwide rule would need to be incorporated into the Clean Air Act permits for the Santa Theresa facility by New Mexico – thus the precise nature of the application of a future national standard is entirely hypothetical at this point. Additionally, the United States does

not expect that a court decision on the state-law issues raised in this case would, in any way, impact EPA's ongoing regulatory process.

For the reasons discussed above, this Court should decline to invoke the doctrine of primary jurisdiction to stay or dismiss this action.

Respectfully Submitted,

FOR THE UNITED STATES

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Dated: June XX, 2021

s/
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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing XXXXXXXX with the Clerk of Court using the Court's electronic filing system.

Dated: June XX, 2021

s/